**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES,<br><br>Plaintiffs,<br><br>v.<br><br>ACCORD HEALTHCARE INC. and ACCORD HEALTHCARE INC. USA,<br><br>Defendants. | C.A. No. 1:20-cv-01362-RGA |

**ACCORD HEALTHCARE INC.'S**
**ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Accord Healthcare Inc. ("Accord") responds to the Complaint by Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P. (collectively, "Purdue"), and Rhodes Technologies ("Rhodes") (collectively, "Plaintiffs") as follows. Accord does not purport to answer any allegations on behalf of the named defendant "Accord Healthcare Inc. USA" because, to Accord's knowledge, such an entity does not exist.

## NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 9,763,933 ("the Mannion '933 patent"); 9,775,808 ("the '808 patent"); 9,763,886 ("the '886 patent"); 9,073,933 ("the '933 patent"); 9,522,919 ("the '919 patent"); and 10,407,434 ("the '434 patent) (collectively, "the patents-in-suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 213564 submitted upon information and belief in the name of Defendants to the United States Food and Drug Administration ("FDA").

**ANSWER:** Accord admits that Plaintiffs purport to bring this action for alleged infringement of the Mannion '933 patent, the '808 patent, the '886 patent, the '933 patent, the '919 patent, and the '434 patent under the patent laws of the United States, Title 35, United

States Code. Accord admits that it submitted ANDA No. 213564 in the name of Accord Healthcare Inc. Accord denies any remaining allegations in this paragraph.

2. Plaintiffs seek judgment that Defendants have infringed the Mannion '933, '808, '933, '919 and '434 patents (collectively, "the Orange Book patents"), which are listed in the FDA *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") as covering Purdue's OxyContin® (oxycodone hydrochloride) ("OxyContin®"), an extended-release pain medication. Plaintiffs also seek judgment that Defendants have infringed the '886 patent. Defendants have infringed the Orange Book patents and the '886 patent at least under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 213564, submitted upon information and belief in the name of Defendants to the FDA. Defendants' ANDA seeks approval to market a generic version of Purdue's OxyContin®, which is the subject of approved New Drug Application ("NDA") No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths ("Defendants' ANDA Products").

**ANSWER:** Accord admits that the Mannion '933, '808, '933, '919 and '434 patents are listed in the Orange Book in connection with NDA No. 022272. Accord admits that it filed ANDA No. 213564 under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking FDA approval to market oxycodone hydrochloride tablets. Accord admits that Purdue's OxyContin® is the subject of approved NDA No. 022272. Accord denies any remaining allegations in this paragraph.

## THE PARTIES

3. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an owner of the Mannion '933, '808, '886, '933, '919, and '434 patents, identified in paragraphs 26-31 below. Purdue Pharma is also the holder of approved NDA No. 022272 for OxyContin®, indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Purdue Pharma sells OxyContin® in the United States.

**ANSWER:** Accord admits that Purdue Pharma is an assignee of record for the Mannion '933, '808, '886, '933, '919, and '434 patents. Accord admits that Purdue Pharma is the holder of approved NDA No. 022272 for OxyContin®. Accord lacks knowledge or information

sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

4. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the Mannion '933, '808, '886, '933, '919, and '434 patents, identified in paragraphs 26-31 below.

**ANSWER:** Accord admits that Purdue Pharmaceuticals is an assignee of record for the '808, '886, '933, '919, and '434 patents. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

5. Plaintiff Rhodes Technologies ("Rhodes") is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of the '933, '919 and '434 patents, identified in paragraphs 29-31 below, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin®.

**ANSWER:** Accord admits that Rhodes is an assignee of record for the '933, '919, and '434 patents. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

6. On information and belief, Defendant Accord Healthcare Inc. ("Accord Healthcare") is a company organized and existing under the laws of the State of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

**ANSWER:** Admitted.

7. On information and belief, Defendant Accord Healthcare Inc., USA ("Accord USA") is a corporation organized and existing under the laws of the State of North Carolina, having a place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

**ANSWER:** Denied.

8. On information and belief, Defendants Accord Healthcare and Accord USA are both wholly-owned subsidiaries of Intas Pharmaceuticals Limited.

**ANSWER:** Accord admits that it is a wholly-owned subsidiary of Intas Pharmaceuticals Limited. Accord denies any remaining allegations in this paragraph.

9. On information and belief, Defendants Accord Healthcare and Accord USA develop, manufacture, distribute and/or market pharmaceutical products throughout the United States, including in this judicial district, through their own actions and through the actions of their agents, including Accord USA acting as an agent for Accord Healthcare.

**ANSWER:** Accord admits that it markets and distributes generic pharmaceutical products in the United States. Accord denies any remaining allegations in this paragraph.

10. On further information and belief, Defendants Accord Healthcare and Accord USA are working in concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the Defendants' ANDA Products described in ANDA No. 213564.

**ANSWER:** Denied.

11. On information and belief, Defendants Accord Healthcare and Accord USA closely coordinate their commercial activities and simultaneously share senior corporate officers.

**ANSWER:** Denied.

12. On information and belief, Defendant Accord USA will distribute Defendants' ANDA Products when approved.

**ANSWER:** Denied.

13. On information and belief, Defendants Accord Healthcare and Accord USA were jointly involved in the preparation and submission of Defendants' ANDA.

**ANSWER:** Denied.

14. On further information and belief, if Defendants' ANDA is approved, Defendants Accord Healthcare and Accord USA will be jointly involved in the manufacturing, marketing, distributing and/or sale of Defendants' ANDA Products.

**ANSWER:** Denied.

## SUBJECT MATTER JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**ANSWER:** Accord admits that Plaintiffs purport that this action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Accord denies any remaining allegations in this paragraph.

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Paragraph 16 states a legal conclusion to which no answer is required. To the extent an answer is required, Accord admits that this Court generally has subject matter jurisdiction over a civil action properly alleging infringement of a U.S. patent under 28 U.S.C. §§ 1331 and 1338(a). Accord denies any remaining allegations in this paragraph.

17. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b). Defendants have also agreed not to challenge venue for the purposes of this action.

**ANSWER:** Paragraph 17 states a legal conclusion to which no answer is required. To the extent an answer is required, Accord does not contest venue in this proceeding. Accord denies any remaining allegations in this paragraph.

**PERSONAL JURISDICTION**

18. Defendants have agreed not to challenge personal jurisdiction for the purposes of this action.

**ANSWER:** Accord admits that it agreed not to contest personal jurisdiction in the District of Delaware for the purposes of this case only. Accord denies any remaining allegations in this paragraph.

19. Regardless, this Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia,* their systematic and continuous contacts with Delaware and contacts with Delaware in connection with the submission of Defendants' ANDA, as set forth below.

**ANSWER:** Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

20. On information and belief, Defendants are in the business of preparing generic pharmaceuticals that they distribute in the State of Delaware and throughout the United States.

**ANSWER:** Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

21. On information and belief, if ANDA No. 213564 is approved, the Defendants' ANDA Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

**ANSWER:** Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

22. This Court further has personal jurisdiction over Defendants by virtue of the fact that they directed their "Notice of Paragraph IV Certification" to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware, and Plaintiff Rhodes, which is a general partnership organized and existing under the laws of the State of Delaware.

**ANSWER:** Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

23. This Court further has personal jurisdiction over Defendants by virtue of the fact that Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware, and Plaintiff Rhodes, which is a general partnership organized and existing under the laws of the State of Delaware.

**ANSWER:** Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

24. This Court further has personal jurisdiction over Defendant Accord Healthcare because Defendant Accord Healthcare has been a defendant and counter claimant in several cases in this Court without challenge to the subject matter jurisdiction, venue or personal jurisdiction of this Court. For example, *Otsuka Pharmaceutical Co. et al. v. Accord Healthcare Inc.*, C.A. No. 19-1987-LPS (D. Del.), D.I. 9 (Accord Healthcare's 2/24/20 Answer, Affirmative Defenses And Counterclaims, Paragraphs 8, 9, and 13 ("Accord does not contest that subject matter jurisdiction is proper in this judicial district pursuant to 35 U.S.C. §§ 1331 and 1338(a) for purposes of this civil action only"; "Accord will not contest personal jurisdiction or venue in this Court for purposes of this civil action only"; and "Accord will not contest personal jurisdiction in this Court for purposes of this civil action only.")); *Novartis Pharmaceuticals Corp. v. Accord Healthcare, Inc. et al.*, C.A. No. 18-1043-LPS (D. Del.), D.I. 46 (Accord Healthcare's 8/18/18 Answer To Complaint And Additional Defenses, Paragraphs 12, 13, 216 and 217 ("For purposes of this action only, Accord consents to jurisdiction and venue in the Court"; "For purposes of this action only, Accord does not contest [subject matter] jurisdiction or venue in this Court"; and "For the purpose of this action only, Accord does not contest personal jurisdiction over Accord")); and *Biogen International GmbH et al. v. Accord Healthcare Inc.*,

C.A. No. 17-cv-872-LPS (D. Del.), D.I. 8 (Accord Healthcare's 10/16/17 Answer, Affirmative Defenses, And Counterclaims, Paragraphs 7, 1 [sic], and 3 [sic] (Accord "admits that this Court generally has subject matter jurisdiction over a civil action properly alleging infringement of a U.S. patent under 35 U.S.C. §§ 1331 and 1338(a)"; "does not contest venue or personal jurisdiction in this proceeding"; and "does not contest personal jurisdiction in this proceeding")).

**ANSWER:** Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

25. This Court further has personal jurisdiction over Defendant Accord USA because Defendant Accord USA has been a defendant and counter claimant in several cases in this Court without challenge to the subject matter jurisdiction, venue or personal jurisdiction of this Court. For example, in *Pfizer Inc. et al v. Accord Healthcare Inc. USA*, C.A. No. 13-1155-GMS (D. Del.), Accord USA did not object to personal jurisdiction and venue in Delaware. *See* D.I. 9 (Accord USA's 8/21/13 Answer And Counterclaims, Paragraphs 6 and 7 ("Accord does not contest personal jurisdiction by this Court over Accord for purposes of this action only"; "Accord does not contest venue in this judicial district for purposes of this action only")).

**ANSWER:** Accord does not contest personal jurisdiction in this proceeding. Accord denies any remaining allegations in this paragraph.

## THE PATENTS-IN-SUIT

26. Purdue is the lawful owner of all right, title and interest in the Mannion '933 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The Mannion '933 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the Mannion '933 patent is attached hereto as Exhibit A, which was duly and legally issued on September 19, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

**ANSWER:** Accord admits that Purdue Pharma is an assignee of record of the Mannion '933 patent. Accord admits that the Mannion '933 patent is entitled "TAMPER RESISTANT DOSAGE FORMS." Accord admits that the Mannion '933 patent is listed in the Orange Book in connection with OxyContin®. Accord admits that OxyContin® is the subject of approved NDA No. 022272. Accord admits that Exhibit A purports to be a copy of the Mannion '933 patent. Accord admits that the Mannion '933 patent lists William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors. Accord lacks knowledge or

information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

27. Purdue is the lawful owner of all right, title and interest in the '808 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '808 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '808 patent is attached hereto as Exhibit B, which was duly and legally issued on October 3, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

**ANSWER:** Accord admits that Purdue is an assignee of record of the '808 patent. Accord admits that the '808 patent is entitled "TAMPER RESISTANT DOSAGE FORMS." Accord admits that the '808 patent is listed in the Orange Book in connection with OxyContin®. Accord admits that OxyContin® is the subject of approved NDA No. 022272. Accord admits that Exhibit B purports to be a copy of the '808 patent. Accord admits that the '808 patent lists William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

28. Purdue is the lawful owner of all right, title and interest in the '886 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. A copy of the '886 patent is attached hereto as Exhibit C, which was duly and legally issued on September 19, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

**ANSWER:** Accord admits that Purdue is an assignee of record of the '886 patent. Accord admits that the '886 patent is entitled "TAMPER RESISTANT DOSAGE FORMS." Accord admits that Exhibit C purports to be a copy of the '886 patent. Accord admits that the '886 patent lists William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

29. Purdue and Rhodes are the lawful owners of all right, title, and interest in the '933 patent, titled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-

HYDROXYCODEINONE," including the right to sue and to recover for past infringement thereof. The '933 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '933 patent is attached hereto as Exhibit D, which was duly and legally issued on July 7, 2015, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

**ANSWER:** Accord admits that Purdue and Rhodes are listed as assignees of record of the '933 patent. Accord admits that the '933 patent is entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14- HYDROXYCODEINONE." Accord admits that the '933 patent is listed in the Orange Book in connection with OxyContin®. Accord admits that OxyContin® is the subject of approved NDA No. 022272. Accord admits that Exhibit D purports to be a copy of the '933 patent. Accord admits that the '933 patent lists Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

30. Purdue and Rhodes are the lawful owners of all right, title, and interest in the '919 patent, titled "OXYCODONE COMPOSITIONS," including the right to sue and to recover for past infringement thereof. The '919 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '919 patent is attached hereto as Exhibit E, which was duly and legally issued on December 20, 2016, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

**ANSWER:** Accord admits that Purdue and Rhodes are listed as assignees of record of the '919 patent. Accord admits that the '919 patent is entitled "OXYCODONE COMPOSITIONS." Accord admits that the '919 patent is listed in the Orange Book in connection with OxyContin®. Accord admits that OxyContin® is the subject of approved NDA No. 022272. Accord admits that Exhibit E purports to be a copy of the '919 patent. Accord admits that the '919 patent lists Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

31. Purdue and Rhodes are the lawful owners of all right, title, and interest in the '434 patent, titled "PROCESS FOR PREPARING OXYCODONE COMPOSITIONS," including the right to sue and to recover for past infringement thereof. The '434 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '434 patent is attached hereto as Exhibit F, which was duly and legally issued on September 10, 2019, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

**ANSWER:** Accord admits that Purdue and Rhodes are listed as assignees of record of the '434 patent. Accord admits that the '434 patent is entitled "PROCESS FOR PREPARING OXYCODONE COMPOSITIONS." Accord admits that the '434 patent is listed in the Orange Book in connection with OxyContin®. Accord admits that OxyContin® is the subject of approved NDA No. 022272. Accord admits that Exhibit F purports to be a copy of the '434 patent. Accord admits that the '919 patent lists Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors. Accord lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in this paragraph, and therefore denies them.

**DEFENDANTS' ANDA**

32. On information and belief, on or before August 25, 2020, Defendants filed Defendants' ANDA in the name of Defendants with the FDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Defendants' ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

**ANSWER:** Accord admits that it filed ANDA No. 213564 on or before August 25, 2020, in the name of Accord Healthcare Inc., seeking approval of the ANDA, and that the Reference Listed Drug in the ANDA is OxyContin®, which is the subject of approved NDA No. 022272. Accord denies any remaining allegations in this paragraph.

33. On information and belief, Defendants subsequently submitted in their ANDA a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that, *inter alia*, the Mannion '933, '808, '933, '919 and '434 patents, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, are "invalid, unenforceable,

and/or will not be infringed" by the commercial manufacture, use, offer for sale, sale or importation of the drug products described in Defendants' ANDA.

**ANSWER:** Accord admits that Accord Healthcare Inc. filed ANDA No. 213564 with a Paragraph IV certification with respect to the Mannion '933, '808, '933, '919 and '434 patents. Accord denies any remaining allegations in this paragraph.

34. In a letter dated August 25, 2020, addressed to Plaintiffs and received by Purdue Pharma on or about August 26, 2020, Defendants provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendants' ANDA and Defendants' ANDA Products, and the Orange Book patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

**ANSWER:** Accord admits that Accord Healthcare Inc. sent a letter dated August 25, 2020 to Plaintiffs providing a Notice of Paragraph IV Certification with respect to Accord's ANDA and the Orange Book patents, pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Accord denies any remaining allegations in this paragraph.

35. Defendants' submission of Defendants' ANDA was an act of infringement of the Orange Book patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

36. Plaintiffs commenced this action within the 45-day period after receiving the Notice Letter as described in 21 U.S.C. § 355(j)(5)(B)(iii).

**ANSWER:** Admitted.

## FIRST CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,763,933)

37. Purdue incorporates by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

**ANSWER:** Accord incorporates its answers to each of the prior paragraphs.

38. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the Mannion '933 patent by Defendants.

**ANSWER:** Denied.

39. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the Mannion '933 patent, including but not limited to independent claims 1 and 11, which recite *inter alia*, a cured tablet comprising an extended release matrix, wherein said tablet comprises at least one polyethylene oxide having an approximate molecular weight of 1,000,000 to 15,000,000 and oxycodone, and various claims dependent therefrom.

**ANSWER:** Denied.

40. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the Mannion '933 patent under 35 U.S.C. § 271(a)-(c). Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the Mannion '933 patent.

**ANSWER:** Denied.

41. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the Mannion '933 patent.

**ANSWER:** Denied.

42. Upon information and belief, Defendants have been aware of the existence of the Mannion '933 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the Mannion '933 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

**ANSWER:** Denied.

43. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the Mannion '933 patent. Purdue does not have an adequate remedy at law.

**ANSWER:** Denied.

## SECOND CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,775,808)

44. Purdue incorporates by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

**ANSWER:** Accord incorporates its answers to each of the prior paragraphs.

45. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '808 patent by Defendants.

**ANSWER:** Denied.

46. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '808 patent, including but not limited to independent claims 1 and 11, which recite *inter alia*, a cured tablet comprising an extended release matrix, wherein said tablet comprises at least one polyethylene oxide having an approximate molecular weight of 1,000,000 to 15,000,000 and oxycodone, and various claims dependent therefrom.

**ANSWER:** Denied.

47. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '808 patent under 35 U.S.C. § 271(a)-(c). Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '808 patent.

**ANSWER:** Denied.

48. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '808 patent.

**ANSWER:** Denied.

49. Upon information and belief, Defendants have been aware of the existence of the '808 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '808 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

**ANSWER:** Denied.

50. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '808 patent. Purdue does not have an adequate remedy at law.

**ANSWER:** Denied.

## THIRD CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,763,886)

51. Purdue incorporates by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

**ANSWER:** Accord incorporates its answers to each of the prior paragraphs.

52. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '886 patent by Defendants.

**ANSWER:** Denied.

53. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '886 patent, including but not limited to independent claim 1 which recites *inter alia*, a method of producing a plurality of solid oral extended release pharmaceutical dosage forms comprising the steps of: mixing at least one active agent, at least one high molecular weight polyethylene oxide (PEO) having an approximate molecular weight of from 1 million to 15 million, to provide a PEO composition; compressing the PEO composition to provide a plurality of shaped matrix compositions; curing the shaped matrix compositions by exposure to heated air at a curing temperature that is at least the softening temperature of the high molecular weight PEO for a curing time of at least about 5 minutes, to provide a plurality of cured matrix compositions; cooling the cured matrix compositions; wherein (a) the molecular weight of each PEO is based on rheological measurements; (b) the high molecular weight PEO comprises at least about 30% (by weight) of each dosage form; (c) the total weight of each dosage form is calculated by excluding the combined weight of said film coatings; and (d) each cured matrix composition comprises a solid oral pharmaceutical dosage form that provides an extended release of at least one active agent, and various claims dependent therefrom.

**ANSWER:** Denied.

54. If approved by the FDA, Defendants will infringe the '886 patent by making, using, offering for sale, selling, and distributing products embodying the patented inventions in violation of 35 U.S.C. § 271(a) or (g) and/or by inducing others to make, use, sell, or offer for sale products and methods embodying the patented inventions in violation of 35 U.S.C. § 271(b).

**ANSWER:** Denied.

55. Defendants, through at least their labeling and manufacturing process, will intentionally induce infringement of the '886 patent by at least patients who will take Defendants' ANDA Products, caregivers/healthcare providers who administer the products, and any manufacturers other than Defendants who manufacture Defendants' ANDA Products.

**ANSWER:** Denied.

56. Upon information and belief, Defendants have been aware of the existence of the '886 patent, and have no reasonable basis for believing that the manufacture, use, sale, or offer for sale of Defendants' ANDA Products will not infringe the '886 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

**ANSWER:** Denied.

57. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '886 patent. Purdue does not have an adequate remedy at law.

**ANSWER:** Denied.

**FOURTH CLAIM FOR RELIEF**
**(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,073,933)**

58. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

**ANSWER:** Accord incorporates its answers to each of the prior paragraphs.

59. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '933 patent by Defendants.

**ANSWER:** Denied.

60. On information and belief, the process for making the oxycodone HCl API that Defendants intend to use in Defendants' ANDA Products is covered by one or more claims of the '933 patent, including but not limited to independent claim 10, which recites, *inter alia*, a process of preparing an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodeinone, and various claims dependent therefrom.

**ANSWER:** Denied.

61. If approved by the FDA, Defendants' importation, offer for sale, sale, and/or use of the oxycodone HCl API in Defendants' ANDA Products will infringe one or more claims of the '933 patent under 35 U.S.C. § 271(g).

**ANSWER:** Denied.

62. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '933 patent, including but not limited to independent claims 1 and 16, which recite, *inter alia*, an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodeinone, and various claims dependent therefrom.

**ANSWER:** Denied.

63. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '933 patent under 35 U.S.C. § 271(a)-(c). Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '933 patent.

**ANSWER:** Denied.

64. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '933 patent.

**ANSWER:** Denied.

65. Upon information and belief, Defendants have been aware of the existence of the '933 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '933 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

**ANSWER:** Denied.

66. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '933 patent. Purdue and Rhodes do not have an adequate remedy at law.

**ANSWER:** Denied.

## FIFTH CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 9,522,919)

67. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

**ANSWER:** Accord incorporates its answers to each of the prior paragraphs.

68. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '919 patent by Defendants.

**ANSWER:** Denied.

69. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '919 patent, including but not limited to independent claims 1, 12 and 18, which recite, *inter alia*, an oxycodone hydrochloride composition having ratio of 8α,14-dihydroxy-7,8-dihydrocodeinone to oxycodone HCl is 0.04% or less as measured by HPLC, and various claims dependent therefrom.

**ANSWER:** Denied.

70. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '919 patent under 35 U.S.C. § 271(a)-(c). Since at least the date of the Notice Letter, Defendants have acted with

knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '919 patent.

**ANSWER:** Denied.

71. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '919 patent.

**ANSWER:** Denied.

72. Upon information and belief, Defendants have been aware of the existence of the '919 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '919 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

**ANSWER:** Denied.

73. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '919 patent. Purdue and Rhodes do not have an adequate remedy at law.

**ANSWER:** Denied.

## SIXTH CLAIM FOR RELIEF
## (PATENT INFRINGEMENT OF U.S. PATENT NO. 10,407,434)

74. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

**ANSWER:** Accord incorporates its answers to each of the prior paragraphs.

75. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '434 patent by Defendants.

**ANSWER:** Denied.

76. On information and belief, the process for making the oxycodone HCl API that Defendants intend to use in Defendants' ANDA Products is covered by one or more claims of the '434 patent, including but not limited to independent claim 1, which recites, *inter alia*, a process of purifying oxycodone free base or oxycodone HCl that contains 8α, 14-dihydroxy-7,8-dihydrocodeinone ("8α") or HCl salt thereof, and various claims dependent therefrom.

**ANSWER:** Denied.

77. If approved by the FDA, Defendants' importation, offer for sale, sale, and/or use of the oxycodone HCl API in Defendants' ANDA Products will infringe one or more claims of the '434 patent under 35 U.S.C. § 271(g).

**ANSWER:** Denied.

78. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '434 patent, including but not limited to dependent claim 20, which recites, *inter alia*, purified oxycodone HCl prepared according to the process recited in dependent claim 2, which recites, *inter alia*, the process of independent claim 1 as well as specific ratios of 8α or HCl salt thereof to oxycodone free base or oxycodone HCl at certain stages in the claimed process.

**ANSWER:** Denied.

79. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '434 patent under 35 U.S.C. § 271(a)-(c).

**ANSWER:** Denied.

80. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '434 patent.

**ANSWER:** Denied.

81. On information and belief, Defendants have been aware of the existence of the '434 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '434 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

**ANSWER:** Denied.

82. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '434 patent. Purdue and Rhodes do not have an adequate remedy at law.

**ANSWER:** Denied.

## RESPONSE TO REQUEST FOR RELIEF

Accord denies that Plaintiffs are entitled to any relief described in the section of the Complaint entitled "Request for Relief," and deny that Plaintiffs are entitled to any relief

whatsoever. Accord further denies any allegation in the Complaint not specifically admitted above.

## AFFIRMATIVE DEFENSES

### FIRST AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the Mannion '933 patent.

### SECOND AFFIRMATIVE DEFENSE

The claims of the Mannion '933 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons set forth in Accord's Notice Letter dated August 25, 2020.

### THIRD AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '808 patent.

### FOURTH AFFIRMATIVE DEFENSE

The claims of the '808 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons set forth in Accord's Notice Letter dated August 25, 2020.

### FIFTH AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '886 patent.

**SIXTH AFFIRMATIVE DEFENSE**

The claims of the '886 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

**SEVENTH AFFIRMATIVE DEFENSE**

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '933 patent.

**EIGHTH AFFIRMATIVE DEFENSE**

The claims of the '933 patent are invalid under collateral estoppel at least for the reasons set forth in Accord's Notice Letter dated August 25, 2020.

**NINTH AFFIRMATIVE DEFENSE**

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '919 patent.

**TENTH AFFIRMATIVE DEFENSE**

The claims of the '919 patent are invalid under collateral estoppel at least for the reasons set forth in Accord's Notice Letter dated August 25, 2020.

**ELEVENTH AFFIRMATIVE DEFENSE**

The manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '434 patent.

**TWELFTH AFFIRMATIVE DEFENSE**

The claims of the '434 patent are invalid under collateral estoppel at least for the reasons set forth in Accord's Notice Letter dated August 25, 2020.

**THIRTEENTH AFFIRMATIVE DEFENSE**

The Court lacks subject matter jurisdiction for any cause of action under 35 U.S.C. § 271(a)-(c) because there is no real and immediate case or controversy for Plaintiff's claims under 35 U.S.C. § 271(a), (b), or (c).

**FOURTEENTH AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief may be granted.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs are not entitled to a finding that this case is exceptional under 35 U.S.C. § 285 or otherwise.

**RESERVATION OF DEFENSES**

Defendants reserve the right to assert any and all additional defenses and counterclaims that discovery may reveal.

**COUNTERCLAIMS**

For its counterclaims against Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P. (collectively, "Purdue"), and Rhodes Technologies ("Rhodes") (collectively, "Plaintiffs"), Defendant Accord Healthcare Inc. ("Accord") states as follows:

**THE PARTIES**

1. Accord is a corporation organized under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210B, Durham, NC 27703.

2. On information and belief, Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431.

3. On information and belief, Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893.

4. On information and belief, Rhodes Technologies ("Rhodes") is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816.

**JURISDICTION AND VENUE**

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. The Court has personal jurisdiction over Plaintiffs because Plaintiffs commenced and continue to maintain this action against Accord in this judicial district.

8. Venue for these counterclaims is proper in this judicial District pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b).

**ACTS GIVING RISE TO THESE COUNTERCLAIMS**

9. On September 19, 2017, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 9,763,933 ("the Mannion '933 patent"), entitled "TAMPER RESISTANT DOSAGE FORMS." Purdue claims to be the owner of the Mannion '933 patent by virtue of assignment.

10. On October 3, 2017, the USPTO issued U.S. Patent No. 9,775,808 ("the '808 patent"), entitled "TAMPER RESISTANT DOSAGE FORMS." Purdue claims to be the owner of the '808 patent by virtue of assignment.

11. On September 19, 2017, the USPTO issued U.S. Patent No. 9,763,886 ("the '886 patent"), entitled "TAMPER RESISTANT DOSAGE FORMS." Purdue claims to be the owner of the '886 patent by virtue of assignment.

12. On July 7, 2015, the USPTO issued U.S. Patent No. 9,073,933 ("the '933 patent"), entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE." Purdue and Rhodes claim to be the owner of the '933 patent by virtue of assignment.

13. On December 20, 2016, the USPTO issued U.S. Patent No. 9,522,919 ("the '919 patent"), entitled "OXYCODONE COMPOSITIONS." Purdue and Rhodes claim to be the owner of the '919 patent by virtue of assignment.

14. On September 10, 2019, the USPTO issued U.S. Patent No. 10,407,434 ("the '434 patent), entitled "PROCESS FOR PREPARING OXYCODONE COMPOSITIONS." Purdue and Rhodes claim to be the owner of the '434 patent by virtue of assignment.

15. On information and belief, Purdue Pharma is indicated in the records of the U.S. Food and Drug Administration ("FDA") as the holder of New Drug Application ("NDA") No. 022272 for OXYCONTIN (oxycodone hydrochloride) tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, marketed and sold by Purdue Pharma or its subsidiary under the brand name OxyContin®.

13. On information and belief, Purdue submitted the Mannion '933, '808, '933, '919, and '434 patents for listing in the electronic version of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with OxyContin®.

14. By letter dated August 25, 2020 ("Accord's Notice Letter"), Accord Healthcare Inc. notified Purdue that it had filed Abbreviated New Drug Application ("ANDA") No. 213564 with a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each of the Mannion '933, '808, '933, '919, and '434 patents is invalid, unenforceable, and/or will not be infringed by the products that are the subject of ANDA No. 213564 ("Accord's ANDA Products").

15. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), Accord's Notice Letter included a detailed statement of the factual and legal bases for the certification that each of the Mannion '933, '808, '933, '919, and '434 patents is invalid, unenforceable, and/or will not be infringed by Accord's ANDA Products.

16. Accord's Notice Letter also included an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

18. On October 8, 2020, Plaintiffs filed suit against Accord, alleging infringement of the Mannion '933, '808, '886, '933, '919, and '434 patents.

## FIRST CLAIM FOR RELIEF
## (DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE MANNION '933 PATENT)

19. Accord restates and realleges each of the foregoing paragraphs 1-18 as if fully set forth herein.

20. Plaintiffs have accused Accord of infringing the Mannion '933 patent.

21. Accord denies infringement of the Mannion '933 patent and alleges that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or

imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the Mannion '933 patent.

22. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the alleged infringement of the Mannion '933 patent.

23. Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the Mannion '933 patent.

## SECOND CLAIM FOR RELIEF
## (DECLARATORY JUDGMENT OF INVALIDITY OF THE MANNION '933 PATENT)

24. Accord restates and realleges each of the foregoing paragraphs 1-23 as if fully set forth herein.

25. Plaintiffs have accused Accord of infringing the Mannion '933 patent.

26. Accord denies infringement of the Mannion '933 patent and alleges that the claims of the Mannion '933 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons set forth in Accord's Notice Letter.

27. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the validity of the Mannion '933 patent.

28. Accord is entitled to a judicial declaration that the claims of the Mannion '933 patent are invalid under one or more of 35 U.S.C. § 101 *et seq.*

## THIRD CLAIM FOR RELIEF
## (DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '808 PATENT)

29. Accord restates and realleges each of the foregoing paragraphs 1-28 as if fully set forth herein.

30. Plaintiffs have accused Accord of infringing the '808 patent.

31. Accord denies infringement of the '808 patent and alleges that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '808 patent.

32. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the infringement of the '808 patent.

33. Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '808 patent.

## FOURTH CLAIM FOR RELIEF
## (DECLARATORY JUDGMENT OF INVALIDITY OF THE '808 PATENT)

34. Accord restates and realleges each of the foregoing paragraphs 1-33 as if fully set forth herein.

35. Plaintiffs have accused Accord of infringing the '808 patent.

36. Accord denies infringement of the '808 patent and alleges that the claims of the '808 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*, at least for the reasons set forth in Accord's Notice Letter.

37. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the validity of the '808 patent.

38. Accord is entitled to a judicial declaration that the claims of the '808 patent are invalid under one or more of 35 U.S.C. § 101 *et seq.*

**FIFTH CLAIM FOR RELIEF**
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '886 PATENT)**

39. Accord restates and realleges each of the foregoing paragraphs 1-38 as if fully set forth herein.

40. Plaintiffs have accused Accord of infringing the '886 patent.

41. Accord denies infringement of the '886 patent and alleges that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '886 patent.

42. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the infringement of the '886 patent.

43. Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '886 patent.

**SIXTH CLAIM FOR RELIEF**
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '886 PATENT)**

44. Accord restates and realleges each of the foregoing paragraphs 1-43 as if fully set forth herein.

45. Plaintiffs have accused Accord of infringing the '886 patent.

46. Accord denies infringement of the '886 patent and alleges that the claims of the '886 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq*.

47. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the validity of the '886 patent.

48. Accord is entitled to a judicial declaration that the claims of the '886 patent are invalid under one or more of 35 U.S.C. § 101 *et seq*.

## SEVENTH CLAIM FOR RELIEF
## (DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '933 PATENT)

49. Accord restates and realleges each of the foregoing paragraphs 1-48 as if fully set forth herein.

50. Plaintiffs have accused Accord of infringing the '933 patent.

51. Accord denies infringement of the '933 patent and alleges that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '933 patent.

52. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the infringement of the '933 patent.

53. Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly,

or contributorily, and would not induce infringement of, any valid or enforceable claim of the '933 patent.

**EIGHTH CLAIM FOR RELIEF**
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '933 PATENT)**

54. Accord restates and realleges each of the foregoing paragraphs 1-53 as if fully set forth herein.

55. Plaintiffs have accused Accord of infringing the '933 patent.

56. Accord denies infringement of the '933 patent and alleges that the claims of the '933 patent are invalid under collateral estoppel at least for the reasons set forth in Accord's Notice Letter.

57. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the validity of the '933 patent.

58. Accord is entitled to a judicial declaration that the claims of the '933 patent are invalid under collateral estoppel.

**NINTH CLAIM FOR RELIEF**
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '919 PATENT)**

59. Accord restates and realleges each of the foregoing paragraphs 1-58 as if fully set forth herein.

60. Plaintiffs have accused Accord of infringing the '919 patent.

61. Accord denies infringement of the '919 patent and alleges that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '919 patent.

62. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the infringement of the '919 patent.

63. Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '919 patent.

## TENTH CLAIM FOR RELIEF
## (DECLARATORY JUDGMENT OF INVALIDITY OF THE '919 PATENT)

64. Accord restates and realleges each of the foregoing paragraphs 1-63 as if fully set forth herein.

65. Plaintiffs have accused Accord of infringing the '919 patent.

66. Accord denies infringement of the '919 patent and alleges that the claims of the '919 patent are invalid under collateral estoppel at least for the reasons set forth in Accord's Notice Letter.

67. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the validity of the '919 patent.

68. Accord is entitled to a judicial declaration that the claims of the '919 patent are invalid under collateral estoppel.

## ELEVENTH CLAIM FOR RELIEF
## (DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '434 PATENT)

69. Accord restates and realleges each of the foregoing paragraphs 1-68 as if fully set forth herein.

70. Plaintiffs have accused Accord of infringing the '434 patent.

71. Accord denies infringement of the '434 patent and alleges that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '434 patent.

72. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the infringement of the '434 patent.

73. Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe, either directly, indirectly, or contributorily, and would not induce infringement of, any valid or enforceable claim of the '434 patent.

## TWELFTH CLAIM FOR RELIEF
## (DECLARATORY JUDGMENT OF INVALIDITY OF THE '434 PATENT)

74. Accord restates and realleges each of the foregoing paragraphs 1-73 as if fully set forth herein.

75. Plaintiffs have accused Accord of infringing the '434 patent.

76. Accord denies infringement of the '434 patent and alleges that the claims of the '434 patent are invalid under collateral estoppel at least for the reasons set forth in Accord's Notice Letter.

77. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Accord and Plaintiffs regarding the validity of the '434 patent.

78. Accord is entitled to a judicial declaration that the claims of the '434 patent are invalid under collateral estoppel.

**PRAYER FOR RELIEF**

WHEREFORE, Accord respectfully prays for judgment in its favor and against Plaintiffs:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not infringed, do not infringe, and would not infringe any valid or enforceable claim of the Mannion '933, '808, '886, '933, '919, and '434 patents, either literally or under the doctrine of equivalents;

(b) Declaring that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not induced, do not induce, and would not induce the infringement of any valid or enforceable claim of the Mannion '933, '808, '886, '933, '919, and '434 patents;

(c) Declaring that the manufacture, use, sale, offer for sale, or importation of Accord's ANDA Products have not contributorily infringed, do not contributorily infringe, and would not contributorily infringe any valid or enforceable claim of the Mannion '933, '808, '886, '933, '919, and '434 patents;

(d) Declaring that each of the claims of the Mannion '933, '808, and '886 patents is invalid under one or more of 35 U.S.C. § 101 *et seq.*;

(e) Declaring that each of the claims of the '933, '919, and '434 patents is invalid under collateral estoppel;

(f) Ordering that Plaintiff's Complaint be dismissed with prejudice and judgment entered in favor of Accord;

(g) Declaring this case exceptional and awarding Accord its reasonable attorney's fees and costs of these Counterclaims pursuant to 35 U.S.C. § 285;

(h) Awarding Accord such other relief as the Court may deem just and proper.

Respectfully submitted,

GREENBERG TRAURIG, LLP

*/s/ Benjamin J. Schladweiler*

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